

MAR 17 2004

K440538

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510(k) Summary

**Submitter:** American Medical Systems  
10700 Bren Road West  
Minnetonka, MN 55343  
Phone: 952-933-4666  
Fax: 952-930-6496

**Contact Person:** Denise Thompson

**Date Summary Prepared:** February 27, 2004

**Device Common Name:** Urethral Sling, Surgical Mesh

**Device Trade Name:** BioArc TO™ Subfascial Hammock

**Device Classification Name:** Surgical Mesh, polymeric

**Predicate Device:** BioArc SP™ Sling Kit, K030123  
MONARC™ subfascial hammock, K023516

**Device Description:**

The BioArc TO Subfascial Hammock is a suburethral sling procedure that uses a transobturator surgical approach to treat stress urinary incontinence. It is a sterile, single use procedure kit consisting of two stainless steel helical shaped needle passers and a mesh sling assembly to which graft material is attached.

**Indications for Use:**

BioArc TO Subfascial Hammock is intended for the placement of a suburethral graft for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and / or intrinsic sphincter deficiency.

**Comparison to Predicate Device:**

The BioArc TO brings two currently marketed AMS technologies, the BioArc SP Sling Kit and the Monarc subfascial hammock, together into one procedure.

The Indications for Use, fundamental scientific technology, surgical approach, sling placement, and materials are all the same as one of the two predicates.

**Supporting Information:**

The risk analysis and the verification / validation activities reported in this Special 510(k) application substantiate equivalence to the predicate devices and did not raise any new questions of safety or efficacy.

**Conclusion:**

The BioArc TO Subfascial Hammock is substantially equivalent to its predicates with respect to intended use, technological characteristics, and performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

Ms. Denise Thompson  
Regulatory Specialist  
American Medical Systems, Inc.  
10700 Bren Road West  
MINNETONKA MN 55343

SEP 28 2004

Re: K040538  
Trade/Device Name: AMS BioArc™ TO Subfascial Hammock  
AMS BioArc™ SP Sling Kit  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
Product Code: OTN, PAG  
Dated: March 1, 2004  
Received: March 2, 2004

Dear Ms. Thompson:

This letter corrects our substantially equivalent letter of March 17, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

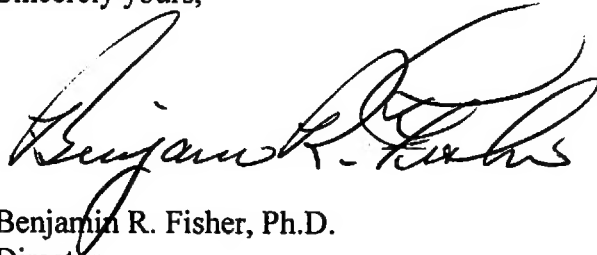
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher". The signature is fluid and cursive, with the first name "Benjamin" being the most prominent part.

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

1.4

## INDICATIONS FOR USE STATEMENT

K040538

510(k) Number (if known):

Device Name: AMS BioArc™ SP Sling Kit

Indications For Use:

The BioArc SP Sling Kit is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and / or intrinsic sphincter deficiency.

Prescription Use   X    
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use         
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

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